> inference that the existing legislation already incorporated the offered change.

*Central Bank*, 114 S. Ct. at 1453 (citations and internal quotation marks omitted); *see also Brecht v. Abrahamson*, 113 S. Ct. 1710, 1719 (1993) ("[a]s a general matter, we are reluctant to draw inferences from Congress' failure to act") (citations and internal quotation marks omitted); *United States v. Wise*, 370 U.S. 405, 411 (1962).

Moreover, as discussed in some comments, bills have been proposed, but not enacted, that would explicitly *exclude* tobacco products from the reach of the Act. *See, e.g.*, S. 1295, 104th Cong., 1st Sess. (1995); H.R. 2265, 104th Cong., 1st Sess. (1995); H.R. 2283, 104th Cong., 1st Sess. (1995). Under the comments' theory, as discussed above, the fact that such legislation was proposed but not enacted would mean that Congress intends FDA to have jurisdiction over tobacco products. Therefore, because bills have been proposed but not enacted on both sides of the issue, Congress would have implicitly both granted jurisdiction to FDA and excluded jurisdiction from FDA. That result would, of course, be absurd.

Other legislative history relied on by the comments also fails to establish that FDA lacks jurisdiction over tobacco products that are intended to affect the structure or function of the body. In asserting that FDA does not have jurisdiction over tobacco products, some comments rely heavily on statements and actions in Congresses that followed the enactment of the 1938 Federal Food, Drug, and Cosmetic Act (e.g., statements by members that FDA lacks jurisdiction over tobacco products). Several comments also cite to remarks regarding FDA's lack of jurisdiction made by individual

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members of Congress who were antismoking advocates. The comments assert that these statements are akin to admissions.

These statements are unpersuasive as evidence of Congress' intent in enacting the "drug" and "device" definitions in sections 201(g)(1)(C) and 201(h)(3) of the Act, 21 U.S.C. 321 (g)(1)(c) and 321(h)(3). The courts have made clear that informal statements by subsequent Congresses cannot negate the broad reach of the language from the 1938 Act granting FDA authority to regulate articles "intended to affect the structure or any function of the body." *See Waterman Steamship Corp. v. United States*, 381 U.S. 252, 269 (1965) ("the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one") (citations and internal quotation marks omitted); *Pennsylvania Med. Soc'y v. Snider*, 29 F.3d 886, 898 (3d Cir. 1994) ("Post-enactment legislative history is not a reliable source for guidance. Even when a subsequent House Committee has actually commented upon an earlier statute, the interpretation carries little weight with the courts") (citations and internal quotation marks omitted); *Central Bank*, 114 S. Ct. at 1452 ("the interpretation given by one Congress (or a committee or Member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute") (citations and internal quotation marks omitted); *Heintz v. Jenkins*, 115 S. Ct. 1489, 1492 (1995) (where Congressman made statement after the statute became law, the statement "is not a statement upon which other legislators might have relied in voting for or against the Act, but it simply represents the views of one informed person on an issue about which others may (or may not) have thought differently").

Furthermore, as other comments argue, neither the Agency nor the congressional committees and members involved were aware, at the time when the statements and

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actions were made, of the new evidence, summarized in section II., above, showing that: (1) nicotine is highly addictive; (2) the vast majority of consumers use tobacco products to satisfy their addiction and for other pharmacological effects; and (3) the tobacco industry has long known that consumers use tobacco products for the pharmacological effects of nicotine and have facilitated these effects through manipulation of nicotine delivery. These comments contend that reliance on congressional statements or actions made before this evidence was known would reward the tobacco industry for concealing evidence about the nature of its products. Other comments assert that the legislative history cited by the tobacco industry is not dispositive in this instance because only now has FDA amassed sufficient evidence to demonstrate that nicotine in tobacco products is intended to act as a drug.

FDA agrees. Evidence that has come to light in the last few years demonstrates that cigarettes and smokeless tobacco are intended to affect the structure and function of the body. Earlier Congresses did not have access to this evidence of intended use. Thus, statements and actions by members of previous Congresses have no bearing on whether the current evidence shows that cigarettes and smokeless tobacco are within FDA's jurisdiction because they are "intended to affect the structure or any function of the body."

### C. OTHER STATUTES DO NOT PRECLUDE OR PREEMPT FDA'S JURISDICTION OVER TOBACCO PRODUCTS

Several comments assert that the Federal Cigarette Labeling and Advertising Act (the Cigarette Act), 15 U.S.C. 1331-1341, and the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act), 15 U.S.C. 4401-4408, which concern health warnings on packaging of cigarettes and packaging and advertising of smokeless tobacco

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respectively, explicitly preempt FDA action concerning the labeling or advertising of tobacco products. Other comments assert that the existence of several statutes relating to tobacco products—including the Cigarette Act and the Smokeless Act, as well as section 1926 of the Public Health Service Act—demonstrates Congress' intent to establish a "comprehensive" tobacco regulation program that somehow implicitly precludes or preempts FDA's regulation of cigarettes under the Act.

The Agency disagrees. None of the statutes cited either expressly or impliedly preempts FDA regulation of tobacco products generally, nor do the statutes cited conflict with the final rule. These comments have misread the Cigarette Act and the Smokeless Act. Both of these statutes contain specific provisions addressing the extent to which FDA and other Federal agencies are preempted from regulating cigarettes and smokeless tobacco. These provisions are narrowly written and do not preempt FDA from asserting jurisdiction when an intent to affect the structure or function of the body can be established. The Cigarette Act, for instance, contains two preemption provisions relating to cigarettes. The first provision is narrowly tailored in scope, applying only to "statement[s] relating to smoking and health . . . on any cigarette package." 15 U.S.C. 1334(a). That provision is not triggered by the content of the final rule because the Agency is not requiring any statements regarding smoking and health on the cigarette package.

The Cigarette Act's second preemption provision, which applies to the advertising and promotion of cigarettes, is expressly directed at State law: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in

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conformity with the provisions of this Act." 15 U.S.C. 1334(b). If Congress had intended to preempt other Federal initiatives by this provision, it would have done so by, for example, adding the words "or Federal" between "State" and "law" in section 1334(b). In fact, Congress did just the opposite. The legislative history of the Cigarette Act establishes that Congress considered and rejected preemption of Federal regulation in the advertising preemption provision. Conf. Rep. 897, 91st Cong., 2d Sess. 2 (1970), *reprinted in* 1970 U.S.C.C.A.N. 2652, 2677. ("The House bill contained a blanket preemption (applicable to all Federal departments and agencies as well as State and local governments) with respect to requiring statements relating to smoking and health in advertisements of cigarettes . . . .The Senate preemption applied only to States and their political divisions. . . . With minor technical amendments the conference version is the same as the Senate amendment.").

Because Congress specifically addressed the question of Federal preemption in the Cigarette Act, the Agency must follow Congress' determination. General preemption jurisprudence (although applicable to preemption of State law, and not controlling in situations involving preemption of Federal law) also counsels against reading the express preemption provision in the Cigarette Act to extend beyond its terms. *See Cippollone v. Liggett Group, Inc.,* 505 U.S. 504, 517 (1992) ("the pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language in § 5 of each Act"); *see also Medtronic, Inc. v. Lohr,* 64 U.S.L.W. 4625 (U.S. Jun. 26, 1996)(rejecting broad interpretation of preemption provision).[1221] Accordingly, the Agency declines to read a

[1221] *See* Preamble to the Final Rule, Section X., for a more detailed discussion of preemption principles.

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blanket preemption of FDA jurisdiction over cigarettes into the Cigarette Act when Congress expressly drafted a narrow preemption provision.

The preemptive reach of the Smokeless Act is also circumscribed to particular areas. *See* 15 U.S.C. 4406(a). The preemption provision in that act applies only to "statement[s] relating to use of smokeless tobacco and health" on packages and advertisements other than outdoor billboard advertisements. *Id.* This narrow provision cannot be read to preempt FDA jurisdiction, which authorizes regulation in a variety of areas unrelated to the specific statements covered by the preemption provision. As described in the preamble to the final rule, FDA is exercising its jurisdiction without imposing requirements that conflict with this provision.

Nor does the existence of other statutes that regulate tobacco impliedly preempt FDA's regulation of tobacco under its authority to regulate drugs and devices. "It is, of course, a cardinal principle of statutory construction that repeals by implication are not favored." *United States v. United Continental Tuna Corp.*, 425 U.S. 164, 168 (1976). Moreover, the doctrine of implied preemption has been applied only in the context of congressional preemption of *State* laws. *See, e.g., Time Warner Cable,* 66 F.3d at 874; *see also Duvall v. Bristol-Myers-Squibb Co.,* 65 F.3d 392, 396 (4th Cir. 1995) ("the doctrine of preemption is based on the Supremacy Clause of the United States Constitution," which is used to invalidate State laws that conflict with Federal legislation), *petition for cert. filed,* 64 U.S.L.W. 3439 (US Dec. 22, 1995) (No. 95-1010). Because the matter here does not involve Federal preemption of State law, the doctrine has no applicability.

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In the absence of an express preemption provision, one Federal statute precludes giving effect to another Federal statute only where there is an irreconcilable conflict between the two laws. *Connecticut Nat'l Bank v. Germain,* 503 U.S. 249, 253 (1992) ("so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (citation omitted); *Morton v. Mancari,* 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective"). As described in detail in the preamble to the final rule, FDA regulation of tobacco products under the authority of the Act does not conflict with other statutes in the current regulatory scheme for tobacco products, and is clearly capable of coexisting with those statutes.

The fact that FDA's jurisdiction over tobacco products may overlap with the jurisdiction of other Federal agencies is not sufficient to invalidate that jurisdiction. FDA has overlapping jurisdiction with other agencies for several products. For example, while FDA regulates pesticides with respect to their content in food, *see* 21 U.S.C. 342 (adulteration), 21 U.S.C. 343 (misbranding), 21 U.S.C. 1401 (pesticide residue monitoring), the Environmental Protection Agency (EPA) regulates the registration, use, and labeling of pesticides with respect to their effect on the environment under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and the U.S. Department of Agriculture is charged with monitoring pesticide research and development to improve methods of pest control, 7 U.S.C. 5881. In addition, both FDA and the U.S. Department of Agriculture regulate meat and poultry products, including animal drug

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residues found within those products. Finally, FDA and the Federal Trade Commission share responsibilities for the regulation of the advertising of drugs and devices.

Other Federal agencies have overlapping and complementary jurisdiction that arises from their differing missions and expertise. *See, e.g., Rueth v. U.S. EPA*, 13 F.3d 227, 228 (7th Cir. 1993) (EPA and Army Corps of Engineers have concurrent jurisdiction under the Clean Water Act); *Public Utility Dist. No. 1 v. Bonneville Power Admin.*, 947 F.2d 386, 395 (9th Cir. 1991) (the Federal Energy Regulatory Commission has concurrent jurisdiction with other Federal agencies, as well as States, over hydroelectric projects), *cert. denied*, 503 U.S. 1004 (1992); *United Packinghouse, Food and Allied Workers Int'l Union, AFL-CIO v. NLRB*, 416 F.2d 1126, 1133-1134 n.11 (D.C. Cir.) (National Labor Relations Board and the Equal Employment Opportunity Commission have concurrent jurisdiction over racial discrimination claims), *cert. denied*, 396 U.S. 903 (1969). Accordingly, the mere fact that other agencies regulate tobacco for certain purposes does not mean that FDA lacks jurisdiction.

### D. RESPONSE TO COMMENTS

Most of the comments received on this issue have been addressed in the preceding discussion. The remaining comments are addressed below.

1. Many of the comments regarding congressional intent rely primarily on attenuated inferences. For example, several comments assert that, because Congress exempted tobacco from the reach of other statutes, such an exemption should be found by implication in the Act. Similarly, another comment asserts that, because tobacco, drugs, and devices are each exempted under the Toxic Substances Control Act, Congress clearly believed that tobacco products were not drugs or devices. FDA disagrees. If the

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reasoning reflected in these comments were adopted, Congress would be legislating by inference. Moreover, as discussed previously in this section, earlier Congresses did not have access to the new evidence on the intended use of tobacco products. This change in the evidence makes it especially inappropriate to construe such specific and limited past congressional actions so expansively.

2. One comment argues that under *Flood v. Kuhn,* 407 U.S. 258 (1972), FDA is precluded from asserting jurisdiction over cigarettes and smokeless tobacco because the tobacco industry has relied on previous Agency statements that it lacked jurisdiction over tobacco products without claims.

FDA disagrees that the decision in *Flood* precludes FDA's assertion of jurisdiction over tobacco products that are intended to affect the structure or function of the body. *Flood* is inapplicable to tobacco products on at least two grounds. First, the *Flood* court, noting that baseball is "an exception and an anomoly," held that the antitrust laws could not be applied to baseball to invalidate baseball's "reserve system" for players without new legislation, based in part on baseball's "unique place in our American heritage." 407 U.S. at 266, 282. Cigarettes and smokeless tobacco occupy a very different place in American life. Tobacco products, unlike baseball, are responsible for the deaths of over 400,000 Americans each year. The Supreme Court has refused to extend the principle upheld in *Flood* beyond baseball even to other professional sports. *See, e.g., Haywood v. National Basketball Association,* 401 U.S. 1204 (1971); *Radovich v. National Football League,* 352 U.S. 445 (1957); *United States v. International Boxing Club,* 348 U.S. 236 (1955). It is inconceivable that the principle extends to bar the application of public health statutes to products previously unregulated by those statutes.

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Second, the court in *Flood* was concerned about the retroactive application of its decision to an industry that had relied on its exemption from the antitrust laws. There is no evidence that the tobacco industry has relied to its detriment on any belief that tobacco products without claims are not subject to FDA jurisdiction. In *Flood,* there was ample evidence of such reliance; the baseball industry had set up an elaborate contracting system, in place since 1887, that would plainly violate the antitrust laws, in reliance on Supreme Court holdings that baseball was exempt from those laws. The plaintiff in the case sought to have that system invalidated retroactively. The tobacco industry has pointed to no evidence of reliance in the form of actions it has taken that plainly violate the Federal Food, Drug, and Cosmetic Act and that the Agency is seeking to remedy retroactively. The industry is simply interested in maintaining its ability to sell its products free of FDA regulation. Moreover, even had the industry relied on the absence of comprehensive FDA regulation, such reliance would have been inappropriate given the tobacco industry's failure to disclose information relevant to the intended use of cigarettes and smokeless tobacco.

In fact, internal tobacco company documents show that the tobacco industry has not acted in reliance on the belief that tobacco products without claims are always outside FDA's jurisdiction. These documents disclose that members of the industry were aware that evidence other than claims could be used to declare jurisdiction over tobacco products and took steps to avoid the disclosure of such evidence. For example, a Brown & Williamson memorandum submitted to the record in this proceeding reveals that a company lawyer recommended to the president and chief executive officer of Brown & Williamson that the company not become involved in the sale of nicotine patches, stating: